

CLAIM AMENDMENTS

Listing of Claims:

1. (Canceled)
2. (Currently Amended) An injectable depot gel composition comprising:
 - (a) a low molecular weight bioerodible, biocompatible polymer;
 - (b) a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof, said solvent having miscibility in water of less than or equal to 7% at 25°C, and present in an amount effective to plasticize the polymer and form a gel therewith; and
 - (c) a beneficial agent; wherein said composition retains a gel-like consistency after implantation and the low molecular weight polymer and solvent are [[is]] selected to provide a gel composition that is sufficient to deliver the beneficial agent in a controlled manner over a duration of less than about seven days.

Claims 3-6. (Canceled)

7. (Previously Presented) The injectable depot composition of claim 2, wherein the solvent is a mixture of an aromatic alcohol and an ester of an aromatic acid.
8. (Original) The injectable depot composition of claim 7, wherein the aromatic alcohol is benzyl alcohol and the ester of an aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.
9. (Original) The injectable depot composition of claim 8, wherein the ester of an aromatic acid is benzyl benzoate and the lower alkyl ester of an aromatic acid is ethyl benzoate.

10. **(Previously Presented)** The injectable depot composition of claim 2 wherein the low molecular weight polymer has a molecular weight ranging from about 3000 to about 10,000 Daltons.

11. **(Previously Presented)** The injectable depot composition of claim 2, wherein the low molecular weight polymer has a molecular weight ranging from about 3000 to about 8,000 Daltons.

12. **(Previously Presented)** The injectable depot composition of claim 2, wherein the low molecular weight polymer has a molecular weight ranging from about 4000 to about 6,000 Daltons.

13. **(Previously Presented)** The injectable depot composition of claim 2, wherein the low molecular weight polymer has a molecular weight of about 5000 Daltons.

14. **(Previously Presented)** The injectable depot composition of claim 2, wherein the polymer is a polylactide, polyglycolide, polyanhydride, polyamine, polyesteramide, polyorthoester, polydioxanone, polyacetal, polyketal, polycarbonate, polyphosphoester, polyorthocarbonate, polyphosphazene, succinate, poly(malic acid), poly(amino acid), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, chitin, chitosan, hyaluronic acid or a copolymer, terpolymer or mixture thereof.

15. **(Previously Presented)** The injectable depot composition of claim 2, wherein the polymer is a lactic acid polymer.

16. **(Original)** The injectable depot composition of claim 15, wherein the polymer is a copolymer of lactic acid and glycolic acid.

17. **(Previously Presented)** The injectable depot composition of claim 2 comprising about 5 wt.% to about 90 wt.% of the biodegradable, biocompatible polymer and wherein

the polymer is a lactic acid polymer having a weight average molecular weight in the range of about 3,000 to about 10,000 Daltons.

18. **(Previously Presented)** The injectable depot composition of claim 2, wherein the polymer is present in said gel in an amount of about 10 wt.% to about 85 wt.% of the gel.

19. **(Previously Presented)** The injectable depot composition of claim 2, wherein the polymer is present in said gel in an amount of about 35 wt.% to about 65 wt.% of the gel.

20. **(Previously Presented)** The injectable depot composition of claim 2, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

21. **(Previously Presented)** The injectable depot composition of claim 2 wherein the beneficial agent is a drug, protein, enzyme, hormone, polynucleotide, nucleoprotein, polysaccharide, glycoprotein, lipoprotein, polypeptide, steroid, analgesic, local anesthetic, antibiotic agent, chemotherapeutic agent, immunosuppressive agent, anti-inflammatory agent, antiproliferative agent, antimitotic agent, angiogenic agent, antipsychotic agent, central nervous system (CNS) agent, anticoagulant, fibrinolytic agent, growth factor, antibody, or ocular drug.

22. **(Previously Presented)** The injectable depot composition of claim 2 wherein the beneficial agent is an analgesic, local anesthetic, antibiotic agent, anti-inflammatory agent, antipsychotic agent, or anticoagulant.

23. **(Previously Presented)** The injectable depot composition of claim 2 wherein the beneficial agent is present in an amount of from 0.1 to 50% by weight of the combined amounts of the polymer, the solvent and the beneficial agent.

24. **(Previously Presented)** The injectable depot composition of claim 2 wherein the beneficial agent is in the form of particles dispersed or dissolved in the gel.

25. **(Previously Presented)** The injectable depot composition of claim 24 wherein the particles have an average particle size of from 0.1 to 250 microns.

26. **(Previously Presented)** The injectable depot composition of claim 24 wherein the particles further comprise a component selected from the group consisting of a stabilizing agent, bulking agent, chelating agent and a buffering agent.

Claims 27-28. **(Canceled)**.

29. **(Currently Amended)** An injectable depot gel composition comprising:

(a) approximately 5 wt.% to approximately 90 wt.% of a low molecular weight biodegradable, biocompatible lactic acid polymer having a weight average molecular weight in the range of approximately 1,000 to approximately 10,000 Daltons;

(b) a solvent selected from the group consisting of an aromatic alcohol, an ester of an aromatic acid, and mixtures thereof, said solvent having miscibility in water of less than or equal to 7% at 25°C, and present in an amount effective to plasticize the polymer and form a gel therewith; and

(c) a beneficial agent; wherein said composition retains a gel-like consistency after implantation and the low molecular weight polymer and solvent are [[is]] selected to provide a gel composition that is sufficient to deliver the beneficial agent in a controlled manner over a duration of less than about seven days.

30. **(Previously Presented)** The injectable depot composition of claim 29 wherein the lactic acid polymer has a molecular weight ranging from about 3000 to about 10,000 Daltons.

31. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer has a molecular weight ranging from about 3000 to about 8,000 Daltons.

32. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer has a molecular weight ranging from about 4000 to about 6,000 Daltons.

33. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer has a molecular weight of about 5000 Daltons.

34. **(Previously Presented)** The injectable depot composition of claim 29, wherein the polymer is a polylactide, polyglycolide, polyanhydride, polyamine, polyesteramide, polyorthoester, polydioxanone, polyacetal, polyketal, polycarbonate, polyphosphoester, polyorthocarbonate, polyphosphazene, succinate, poly(malic acid), poly(amino acid), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, chitin, chitosan, hyaluronic acid or a copolymer, terpolymer or mixture thereof.

35. **(Canceled).**

36. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer is a copolymer of lactic acid and glycolic acid.

37. **(Canceled).**

38. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer is present in said gel in an amount of about 10 wt.% to about 85 wt.% of said gel.

39. **(Previously Presented)** The injectable depot composition of claim 29, wherein the lactic acid polymer is present in said gel in an amount of about 35 wt.% to about 65 wt.% of said gel.

Claims 40-43. **(Canceled).**

44. **(Previously Presented)** The injectable depot composition of claim 29, wherein the solvent is a mixture of an aromatic alcohol and an ester of an aromatic acid.

45. **(Original)** The injectable depot composition of claim 44, wherein the aromatic alcohol is benzyl alcohol and the ester of an aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.

46. **(Original)** The injectable depot composition of claim 45, wherein the ester of an aromatic acid is benzyl benzoate and the lower alkyl ester of an aromatic acid is ethyl benzoate.

47. **(Original)** The injectable depot composition of claim 44, wherein the ratio of the aromatic alcohol to the ester of an aromatic acid is in the range of about 1% to about 99% by weight.

48. **(Previously Presented)** The injectable depot composition of claim 44, wherein the ratio of the aromatic alcohol to the ester of an aromatic acid is in the range of about 20% to about 80% by weight.

49. **(Previously Presented)** The injectable depot composition of claim 45 wherein the lactic acid polymer has a weight average molecular weight in the range of about 3,000 to about 10,000 Daltons.

50. **(Previously Presented)** The injectable depot composition of claim 29, further including at least one of the following: a pore former; a solubility modulator for the beneficial agent; and an osmotic agent.

51. **(Previously Presented)** The injectable depot composition of claim 29 wherein the beneficial agent is a drug, protein, enzyme, hormone, polynucleotide, nucleoprotein, polysaccharide, glycoprotein, lipoprotein, polypeptide, steroid, analgesic, local anesthetic, antibiotic agent, chemotherapeutic agent, immunosuppressive agent, anti-inflammatory agent, antiproliferative agent, antimitotic agent, angiogenic agent, antipsychotic agent, central nervous system (CNS) agent, anticoagulant, fibrinolytic agent, growth factor, antibody, or ocular drug.

52. **(Previously Presented)** The injectable depot composition of claim 29 wherein the beneficial agent is an analgesic, local anesthetic, antibiotic agent, anti-inflammatory agent, antipsychotic agent, or an anticoagulant.

53. **(Previously Presented)** The injectable depot composition of claim 29 wherein the beneficial agent is present in an amount of from 0.1 to 50% by weight of the combined amounts of the polymer, the solvent and the beneficial agent.

54. **(Previously Presented)** The injectable depot composition of claim 29 wherein the beneficial agent is in the form of particles dispersed or dissolved in the gel.

55. **(Previously Presented)** The injectable depot composition of claim 54 wherein the particles have an average particle size of from 0.1 to 250 microns.

56. **(Previously Presented)** The injectable depot composition of claim 54 wherein the particles further comprise a component selected from the group consisting of a stabilizing agent, bulking agent, chelating agent and a buffering agent.

Claims 57-58. (Canceled).

59. (Currently Amended) An injectable depot gel composition comprising:

(a) approximately 5 wt.% to approximately 90 wt.% of a low molecular weight poly(lactide-co-glycolide) (PLGA) copolymer having a weight average molecular weight in the range of approximately 3,000 to approximately 10,000 Daltons;

(b) approximately 5 wt.% to approximately 90 wt.% of a solvent selected from the group consisting of an aromatic alcohol, an ester of an aromatic acid, and mixtures thereof, said solvent having miscibility in water of less than or equal to 7% at 25°C, and present in an amount effective to plasticize the polymer and form a gel therewith; and

(c) a beneficial agent; wherein said composition retains a gel-like consistency after implantation and the low molecular weight polymer and solvent are [[is]] selected to provide a gel composition that is sufficient to deliver the beneficial agent in a controlled manner over a duration of less than about seven days.

60. (Original) The injectable depot composition of claim 59, wherein the aromatic alcohol is benzyl alcohol and the ester of an aromatic acid is benzyl benzoate.

Claims 61-104. (Canceled).

105. (Currently Amended) A kit for administration of a beneficial agent to a subject comprising:

(a) a low molecular weight bioerodible, biocompatible polymer;
(b) a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof, said solvent having miscibility in water of less than or equal to 7% at 25°C, and present in an amount effective to plasticize the polymer and form a gel therewith; and

(c) a beneficial agent; and optionally, one or more of the following:

an emulsifying agent;

a pore former;

a solubility modulator for the beneficial agent, optionally associated with the beneficial agent; and
an osmotic agent;

wherein at least the beneficial agent, optionally associated with the solubility modulator, is maintained separated from the solvent until the time of administration of the beneficial agent to a subject, and,

wherein said kit is selected to provide a composition that retains a gel-like consistency after implantation and the composition is sufficient to deliver the beneficial agent in a controlled manner over a duration of less than about seven days.

106. **(Previously Presented)** The injectable depot composition of claim 2, wherein the polymer is a polylactide, polyglycolide, or a copolymer, terpolymer or mixture thereof.

107. **(Previously Presented)** The injectable depot composition of claim 2 wherein the solvent is an aromatic alcohol.

108. **(Previously Presented)** The injectable depot composition of claim 107 wherein the aromatic alcohol is benzyl alcohol.

109. **(Previously Presented)** The injectable depot composition of claim 2 wherein the solvent is an ester of an aromatic acid.

110. **(Previously Presented)** The injectable depot composition of claim 109 wherein the ester of an aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.

111. **(Previously Presented)** The injectable depot composition of claim 110 wherein the lower alkyl ester is ethyl benzoate and the aralkyl ester is benzyl benzoate.

112. **(Previously Presented)** The injectable depot composition of claim 2 wherein the polymer is present in said gel in an amount of about 5 wt.% to about 90 wt.% of the gel.

113. **(Previously Presented)** The injectable depot composition of claim 17 wherein the lactic acid polymer is a copolymer of lactic acid and glycolic acid.

114. **(Previously Presented)** The injectable depot composition of claim 17 wherein the lactic acid polymer is present in said gel in an amount of about 10 wt.% to about 85 wt.% of the gel.

115. **(Previously Presented)** The injectable depot composition of claim 17 wherein the lactic acid polymer is present in said gel in an amount of about 35 wt.% to about 65 wt.% of the gel.

116. **(Previously Presented)** The injectable depot composition of claim 29, wherein the polymer is a polylactide, polyglycolide, or copolymer, terpolymer or mixture thereof.

117. **(Previously Presented)** The injectable depot composition of claim 29 wherein the solvent is an aromatic alcohol.

118. **(Previously Presented)** The injectable depot composition of claim 117 wherein the aromatic alcohol is benzyl alcohol.

119. **(Previously Presented)** The injectable depot composition of claim 29 wherein the solvent is an ester of an aromatic acid.

120. **(Previously Presented)** The injectable depot composition of claim 119 wherein the ester of an aromatic acid is a lower alkyl ester or an aralkyl ester of benzoic acid.

121. **(Previously Presented)** The injectable depot composition of claim 120 wherein the lower alkyl ester is ethyl benzoate and the aralkyl ester is benzyl benzoate.

122. **(Previously Presented)** The injectable depot composition of claim 2, wherein about 40% or less of said beneficial agent is delivered over the first 24 hours following injection of said composition.

123. **(Previously Presented)** The injectable depot composition of claim 2, wherein about 30% or less of said beneficial agent is delivered over the first 24 hours following injection of said composition.

124. **(Previously Presented)** The injectable depot composition of claim 2, wherein about 20% or less of said beneficial agent is delivered over the first 24 hours following injection of said composition.